Trichomonas POC tests performed by the patient

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NIBIB POCTRN All Hands Meeting
JHU Center for the Development of POCTs for STDs
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http://hopkinsmedicine.org/medicine/std
Background: U.S. Estimates

Estimated Prevalence of Sexually Transmitted Infections in the U.S. (Total 110,197,000)

Estimated New Sexually Transmitted Infections in the U.S. Each Year (Total 19,738,800)

• Cost of incident infections in 1 year: $15.6 B
  • Does not include indirect costs (productivity)
  • Does not include intangible costs (pain)
  • Viral infections make up 95% of cost
  • “Curable” STIs annual cost: $742M
  • Costs would be even greater without prevention efforts

Barriers to screening for Chlamydia

Barriers for Providers
1. Lack of reimbursement for time required
2. Lack of awareness that patients are sexually active
3. Lack of knowledge that screening can be performed without a pelvic exam

Barriers to Patients
1. Inability to pay copayment of test
2. Lack of knowledge of the asymptomatic nature, high prevalence, and possible adverse long-term reproductive effects of chlamydia infection
3. Privacy, embarrassment, confidentiality

Hypothesis: persons can be empowered to self sample or test at home via the Internet.
Objectives

- Discuss self-testing for POC assay for Trichomonas vaginalis
  - IWTK website testing
  - Emergency Department testing
IWTK Methods

- Order a kit on line; & select Rx clinic
- Kit mailed to home
- Collect sample at home
- Mail kit to lab
- Text or Email sent for when results are ready
- Patient obtains results on line and attends clinic of choice receives results
- Attend a clinic for Rx

2013-15
<table>
<thead>
<tr>
<th>Gender</th>
<th>Area</th>
<th>Sample Size</th>
<th>Year</th>
<th>CT Prevalence</th>
<th>GC Prevalence</th>
<th>TV Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>Vaginal</td>
<td>6207</td>
<td>2004</td>
<td>7.2%</td>
<td>0.8%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Female</td>
<td>Rectal</td>
<td>1055</td>
<td>2009</td>
<td>7.4%</td>
<td>1.0%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Male</td>
<td>Penile</td>
<td>3279</td>
<td>2006</td>
<td>8.2%</td>
<td>0.8%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Male</td>
<td>Rectal</td>
<td>632</td>
<td>2009</td>
<td>7.8%</td>
<td>4.6%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>
### Yearly Internet Tests

<table>
<thead>
<tr>
<th>Kits Tested</th>
<th>Vaginal</th>
<th>Female</th>
<th>Rectal</th>
<th>Penile</th>
<th>Male</th>
<th>Rectal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>749</td>
<td>155</td>
<td>421</td>
<td>103</td>
<td></td>
<td></td>
<td>1515</td>
</tr>
<tr>
<td>2012</td>
<td>961</td>
<td>221</td>
<td>572</td>
<td>99</td>
<td></td>
<td></td>
<td>1853</td>
</tr>
<tr>
<td>2013</td>
<td>907</td>
<td>221</td>
<td>688</td>
<td>148</td>
<td></td>
<td></td>
<td>1964</td>
</tr>
<tr>
<td>2014</td>
<td>821</td>
<td>214</td>
<td>556</td>
<td>182</td>
<td></td>
<td></td>
<td>1773</td>
</tr>
</tbody>
</table>

### Kits requested:
- 2011: 3,572
- 2012: 3,599
- 2013: 3,035
- 2014: 2,722

### Return rate:
- 2004-7 ~30%
- 2011: 42.4%
- 2012: 51.5%
- 2013: 64.7%
- 2014: 65.1%

Postage ($2.40) required for return kits as of July 2014
Self-Collection of Vaginal Swab
ATTENTION: Read ALL instructions before you begin!

STEP 1
Wash your hands thoroughly.

STEP 2
Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina—such as sitting on the toilet, or standing with one foot on a chair, or any position that you would use to insert a tampon.

STEP 3
Take the sealed swab out of the package. Open the swab. Twist first to break seal. Then pull. The swab will stay attached to the red cap.

Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

STEP 4
Insert the white tip of the swab about one inch inside the opening of your vagina.

STEP 5
Rotate the swab for 15 seconds, making sure that the swab touches the walls of your vagina so that moisture is absorbed into the swab.

STEP 6
Remove the swab from your vagina. Don’t let the tip of the swab touch anything else.

STEP 7
Place used swab back into the transport tube. Close tightly to prevent leakage.

STEP 8
Place closed tube into the red plastic zip-lock bag. Seal the bag.

STEP 9
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It’s already addressed and postage is paid, so you don’t need to do anything else.

Peel off adhesive to reveal seal.
**Self-Collection of Penile Swab**

**ATTENTION:** Read ALL instructions before you begin!

**STEP 1**
Take the sealed swab out of the package. Open the swab.

Twist first to break seal.

Then pull. The swab will stay attached to the red cap.

Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

**STEP 2**
Roll the swab just at the tip or inside the opening to the penis through which you pass urine (pee). Roll the swab completely around the opening to get the best specimen. It is not necessary to put the swab deep inside the hole (urethra opening).

Roll the swab around the edges of the urethra opening. (The swab can touch the edges of the hole, but don’t push it inside.)

**STEP 7**
Place used swab back into the transport tube. Close tightly to prevent leakage.

**STEP 8**
Place closed tube into the red plastic zip-lock bag. Seal the bag.

**STEP 9**
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It’s already addressed and postage is paid, so you don’t need to do anything else.
Self-Collection of Rectal Swab

ATTENTION: Read ALL instructions before you begin!

STEP 1
Wash your hands thoroughly.

STEP 2
Unopened Swab
Either squat down, or lift one leg on a toilet, ledge, or chair (as shown). Pull underwear down or off.

STEP 3
Open the swab. Do NOT TOUCH THE TIP OF THE SWAB.
- Twist first to break seal.
- Then pull. The swab will stay attached to the red cap.
- Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

STEP 4
With your dominant hand (right if you're right-handed, left if you're left-handed), grip the opened swab 1.5" away from the tip of the swab (just below the first notch). Do NOT TOUCH THE TIP OF THE SWAB.
- 1 1/2 inches (just below the first notch)

STEP 5
With your other hand, position your bare buttock and lift one cheek for easy access to the rectum. Do NOT use anything on your rectum or the swab.

STEP 6
Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.

STEP 7
Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there, for stability. (The swab should stay where it is—only your fingers should move.)

STEP 8
Gently rub the swab in a circle, touching the walls of your rectum, to collect the specimen.

STEP 9
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

STEP 10
Place used swab back into the transport tube. Close tightly to prevent leakage.

STEP 11
Place closed tube into the red plastic zip-lock bag. Seal the bag.

STEP 12
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It's already addressed and postage is paid, so you don't need to do anything else.
Female Testing Kit Contents

Contact Form

I Want The Kit

Female Testing Kit

READ ALL INSTRUCTIONS BEFORE YOU START

DO NOT BEND OR FOLD

UN3373

Frozen
Refrigerate
Room Temp

STAT

Chlamydia Self-Test

Please don't send this sheet back to the lab - the sample is to be kept for your records.

Johns Hopkins Medicine

Low Risk
OSOM Test Procedure:

1. Insert swab into buffer.
2. Mix Swab in Buffer. Vigorously mix by rotating swab forcefully against the side of the vial at least 10 times.
3. Squeeze liquid from swab and discard swab.
4. Add Test Stick and Incubate. Place absorbent end of test stick into the solution and incubate for 10 min.

- **Positive**: A blue Test Line and a red Control Line.
- **Negative**: A red Control Line but no blue Test Line.
- **Invalid**: If no red Control Line appears or background color makes reading the red Control Line impossible.
Trichomonas IWTK Home Test

IWTK is recruiting for a Trich study. Would like you to participate?

Why is this research being done?

*Trichomonas vaginalis* is a common sexually transmitted infection of the genital tract that can infect both men and women. Rapid diagnosis and correct treatment are very important in the management of genital tract infections and help to prevent serious complications.

This research is being done to evaluate the acceptability and accuracy of performing an investigational, single-use, rapid point-of-care test for *Trichomonas vaginalis* at home by participants from the ‘I Want the Kit’ (IWTK) project.

The word “investigational” means the single-use Trichomonas Rapid Test is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies.

We will ask you to run the investigational, single-use Trichomonas Rapid Test (which is similar to the OSOM® Trichomonas Rapid Test which is FDA-approved and CLIA-waived).

We want to find out if the test is easy to perform, and to compare the results that you get at home with the results that the laboratory gets from the swab that you collect and mail back for testing.

What will happen if you join this study?

If you agree to be in this study, we will send you a single-use Trichomonas Rapid Test with your IWTK Vaginal Kit and ask you to do the following things:
Trichomonas Home Test Analysis

• 567 Eligible unique women (>18yr) viewed website

• 187/567 (33%) Expressed interest/met requirements

• 173/187 (92.5%) Coordinator was able to contact and speak with potential participant about the study

• 134/173 (77.5%) Signed consent form/TV study kit was mailed; [39 not enroll or never consented]

• 86/134* (64.2%) Used TV study kit/ Completed survey/ Entered results/ returned SOC swab for testing; 6 more completed survey but not return SOC kit = 92

*38 still pending; 4 cancelled since SOC results available before study results entered by participant
## Trichomonas Home Test Analysis

<table>
<thead>
<tr>
<th>Question, N = 92</th>
<th>Easy</th>
<th>Somewhat Easy</th>
<th>Not Easy</th>
</tr>
</thead>
<tbody>
<tr>
<td>How easy was it for you to collect the vaginal specimen correctly?</td>
<td>88 (95.6%)</td>
<td>3 (3.3%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>How easy was it for you to read the test strip and interpret (tell) the result?</td>
<td>84 (91.3%)</td>
<td>6 (6.5%)</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>Overall, how easy was it for you to perform the test?</td>
<td>85 (92.4%)</td>
<td>5 (5.4%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Do you believe that the rapid trichomonas test result was correct for the sample that you collected?</td>
<td>52 (56.5%)</td>
<td>39 (42.4%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Question</td>
<td>Trust very much</td>
<td>Trust Somewhat</td>
<td>Do Not Trust</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>----------------</td>
<td>--------------</td>
</tr>
<tr>
<td>How much do you trust the result of the rapid trichomonas test that you collected and tested?</td>
<td>60 (65.2%)</td>
<td>31 (33.7%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Would you test yourself at home for trichomonas if the rapid trichomonas test were available over-the-counter?</td>
<td>77 (83.7%)</td>
<td>14 (15.2%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>What is the maximum price you would pay to purchase a rapid trichomonas test over-the-counter, if available?</td>
<td>42 (45.6%)</td>
<td>37 (40.2%)</td>
<td>3 (14.1%)</td>
</tr>
</tbody>
</table>

$10  
$20  
$30
**Based on your experience, would you prefer to test yourself for trichomonas at home or would you prefer a healthcare provider/laboratory collect and perform your test?**

1. Prefer self-testing 54 (58.7%)
2. Prefer healthcare provider/laboratory 8 (8.7%)
3. No Preference 29 (31.5%)
   No Response 1 (1.1%)

**If you went to a clinic, doctor’s office, or emergency room to see a healthcare provider, which would you prefer?**

1. To have the healthcare provider collect your sample and perform the test 33 (35.9%)
2. To collect the sample yourself and have the healthcare provider perform the test 30 (32.6%)
3. To collect the sample yourself and perform the test yourself in the clinic/doctor’s office/ER 2 (2.2%)
4. No Preference 27 (29.3%)
# Trichomonas Home Test Analysis

<table>
<thead>
<tr>
<th>Interpretation of self-test result by participant</th>
<th>Positive</th>
<th>Negative</th>
<th>SOC swab not returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>1*</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>(* vaginal &amp; rectal TV+ by SOC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>82§</td>
<td>4</td>
</tr>
<tr>
<td>(§ 3 of 82 CT+ by SOC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invalid</td>
<td>0</td>
<td>2€</td>
<td>0</td>
</tr>
<tr>
<td>(€ 1 of 2 rectal TV+ by SOC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Don’t Know”</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

There were 4 participants who returned their SOC swab for testing but did not enter their results/interpretation for their self-test or take the survey:
2 = SOC negative. 1 = SOC TV+. 1 = SOC CT+.  

N = 86 GenProbe SOC TV results
SOC swab not returned
IWTK TV POC Conclusions

• Moderate to high patient acceptability

• Loss of patients due to multiple website contacts needed

• Patients can reliably collect, perform and read POC test with kit and web-based instructions

• Low positivity –”Worried Well”
• Evaluate **POC TV testing** (facilitated by touch screen kiosk) in adult female ED patients who are undergoing a gynecologic exam as part of their standard of care clinical evaluation

• Assess patient acceptability and provider ‘utility’

• Assess accuracy of TV POC relative to gold standard testing
• *Trichomonas vaginalis*
  – Most prevalent non-viral STI in the US and globally
  – High rates of under, and over treatment

• POC tests
  – Available, FDA approved
  – Studies (Huppert et al) demonstrating accuracy and acceptability provider and patient self-collected POC TV testing in *pediatric* patients.

• Adult EDs and other high volume episodic care settings
  – Most rely on conventional insensitive diagnostic testing (wet mount)
  – Availability of POC test and kiosk facilitation provided opportunities for improved care large sectors of the population
Methods

- Physician standard of care assessment
- (Patient approached for consent for study)
- Patient self-collects vaginal swab and perform POC Trichomonas Rapid test with customized kiosk facilitated instructions
- Provider collects swab for additional POC TV test that research coordinator performs
- Compare POC testing results with wet mount SOC
  - GenProbe TV assay for discordant results only with callbacks
- Patient and provider acceptability survey
- Provider treats according to clinical judgment
Methods: Kiosk-facilitated POC TV Self-testing

Collecting the vaginal swab:

1. Swab
2. Vaginal opening
3. Specimen

Test Stick Container

Sterile Rayon Blood Application
## Results (85% enrollment completed*)

### Demographics

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>(SD)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n= 124</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td>27.9</td>
<td>87.9</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td>10.5</td>
</tr>
<tr>
<td>Black/African American</td>
<td>109</td>
<td></td>
<td>1.6</td>
</tr>
<tr>
<td>White</td>
<td>13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td>1.6</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic</td>
<td>120</td>
<td></td>
<td>96.8</td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*based on current positivity rates study powered to detect significant differences in sensitivity between POC vs standard of care
### Patient acceptability before self-testing done

<table>
<thead>
<tr>
<th>Question</th>
<th>Will definitely be correct n (%)</th>
<th>Will probably be correct n (%)</th>
<th>Will not be correct n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you believe that the result of the Trichomonas Rapid Test will be correct, for the sample that you collect?</td>
<td>38 (30.6)</td>
<td>64 (51.6)</td>
<td>8 (6.5)</td>
<td>14 (11.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Very much n (%)</th>
<th>Somewhat n (%)</th>
<th>Not at all n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much will you trust the result of the Trichomonas Rapid Test that you collect?</td>
<td>53 (42.7)</td>
<td>61 (49.2)</td>
<td>5 (4.0)</td>
<td>5 (4.0)</td>
</tr>
</tbody>
</table>
## Comparison of patient acceptability before and after self-test

<table>
<thead>
<tr>
<th>Question: How hard will it be/was it for you to do the Trichomonas Rapid Test correctly?</th>
<th>Very hard n (%)</th>
<th>Somewhat hard n (%)</th>
<th>Not at all hard n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>6 (4.8)</td>
<td>35 (28.2)</td>
<td>78 (62.9)</td>
<td>5 (4.0)</td>
</tr>
<tr>
<td>After</td>
<td>7 (5.6)</td>
<td>14 (11.3)</td>
<td>94 (75.8)</td>
<td>9 (7.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question: Do you think testing yourself is a good thing you can do for your health?</th>
<th>Very good n (%)</th>
<th>Somewhat n (%)</th>
<th>Not at all n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>68 (54.8)</td>
<td>45 (36.3)</td>
<td>6 (4.8)</td>
<td>5 (4.0)</td>
</tr>
<tr>
<td>After</td>
<td>89 (71.8)</td>
<td>25 (20.2)</td>
<td>1 (0.8)</td>
<td>9 (7.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question: Do you think you will recommend to a friend that she test herself for Trichomonas?</th>
<th>Yes n (%)</th>
<th>Probably n (%)</th>
<th>No n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>85 (68.5)</td>
<td>24 (19.4)</td>
<td>8 (6.5)</td>
<td>7 (5.6)</td>
</tr>
<tr>
<td>After</td>
<td>96 (77.4)</td>
<td>15 (12.1)</td>
<td>4 (3.2)</td>
<td>9 (7.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question: Would you test yourself at home if the Trichomonas Rapid Test was available over-the-counter?</th>
<th>Would definitely n (%)</th>
<th>Would probably n (%)</th>
<th>Would not n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>83 (66.9)</td>
<td>27 (21.8)</td>
<td>8 (6.5)</td>
<td>6 (4.8)</td>
</tr>
<tr>
<td>After</td>
<td>93 (75.0)</td>
<td>15 (12.1)</td>
<td>6 (4.8)</td>
<td>10 (8.1)</td>
</tr>
</tbody>
</table>
### Patient acceptability after self-test

<table>
<thead>
<tr>
<th>Question</th>
<th>Testing myself is not as good as the clinician n (%)</th>
<th>Testing myself is just as good as the clinician n (%)</th>
<th>Testing myself is better than the clinician n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How did comparing your results to the clinician’s results make you feel about testing yourself?</td>
<td>19 (15.3)</td>
<td>70 (56.5)</td>
<td>20 (16.1)</td>
<td>15 (12.1)</td>
</tr>
</tbody>
</table>

**Question**

- n = 124
## Results: Acceptability

Provider survey following results of OSOM test

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes n (%)</th>
<th>No n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you plan to treat this patient for Trichomonas Vaginalis?</td>
<td>21 (16.9)</td>
<td>98 (79.0)</td>
<td>5 (4.0)</td>
</tr>
<tr>
<td>Did the result of the OSOM Trichomonas Rapid Test impact your management?</td>
<td>51 (41.1)</td>
<td>68 (54.8)</td>
<td>5 (4.0)</td>
</tr>
</tbody>
</table>
### Results

#### READING ACCURACY:
Patient self-test interpretation vs coordinator interpretation

<table>
<thead>
<tr>
<th></th>
<th>TV positive n (%)</th>
<th>TV negative n (%)</th>
<th>Invalid n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Self-Test (rapid TV test)</td>
<td>23 (18.5)</td>
<td>90 (72.6)</td>
<td>2 (1.6)</td>
<td>9 (7.3)*</td>
</tr>
<tr>
<td>Coordinator Interpretation (rapid TV test)</td>
<td>24 (19.3)</td>
<td>88 (71.0)</td>
<td>3 (2.4)</td>
<td>9 (7.3)*</td>
</tr>
</tbody>
</table>

* 9 women did not complete self-testing

2 women incorrectly interpreted their self-test result:
- 1 incorrectly labeled a positive result as negative (very faint test line)
- 1 incorrectly labeled an invalid result as negative (no control line)
## Results

### TEST CONCORDANCE

Provider collected OSOM and wet mount results

<table>
<thead>
<tr>
<th>Test Type</th>
<th>TV positive n (%)</th>
<th>TV negative n (%)</th>
<th>Invalid n (%)</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSOM rapid test</td>
<td>21 (16.9)</td>
<td>98 (79.0)</td>
<td>0 (0.0)</td>
<td>5 (4.0)*</td>
</tr>
<tr>
<td>Wet mount</td>
<td>13 (10.5)</td>
<td>109 (87.9)</td>
<td>0 (0.0)</td>
<td>2 (1.6)**</td>
</tr>
</tbody>
</table>

* 5 women did not receive OSOM rapid testing
** 2 women did not receive wet mount comparison testing

### Discrepant cases:
1 case OSOM positive, wet mount neg (self-test neg; gold standard neg)  
7 cases OSOM positive, wet mount neg (self test pos; gold standard pos)  
- all of these patients were treated

* Comparison of patient self-test (vs provider self test) revealed an additional 3 positive cases that were confirmed by gold standard test  
- all of these patients were ultimately treated
Limitations

• Lack of control (historical analysis planned)

• Relatively small samples size

• TV testing done in context of GC/CT testing and long standing practice of empiric treatment (potential confounder)
Conclusions

• Baseline moderate to high patient acceptability – improved with real-life experience

• Clinicians indicated POC test impacted management in nearly 50% of cases

• Patients reliably collect, perform and read POC test with kiosk instructions

• POC test increased rates of detection of infection
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